

Message

From: Ross, Mary [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=98359CD1F66F46EC91D327E99A3C6909-ROSS, MARY]
Sent: 6/30/2016 11:01:34 PM
To: Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]; Deener, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9a2ff1c086249ea8f6414afde8a5e54-Deener, Kathleen]
CC: Burke, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39ffc3dd34ea495b9a31e61b778fbbec-Burke, Thom]; Bahadori, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]; Kavlock, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eebac67f01094409a7fdaa955a837884-Kavlock, Robert]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]; Thomas, Russell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12f119e7a3ee447499f3d6ab5d20daeb-Thomas, Rus]; Slimak, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=197d6551afaf4d90b087c4d5bf62b53c-Slimak, Mike]
Subject: RE: This should be interesting

Yes, thanks, Lynn and I'll include it again here. The workload could go way up if we are reviewing and responding to loads of alternative draft assessments submitted for the Administrator's consideration. Hopefully not.

(5) GUIDANCE.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator. The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

From: Flowers, Lynn
Sent: Thursday, June 30, 2016 6:15 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Burke, Thomas <Burke.Thomas@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Kavlock, Robert <Kavlock.Robert@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>
Subject: Re: This should be interesting

Deliberative Process / Ex. 5

Sent from my iPhone

On Jun 30, 2016, at 6:05 PM, Deener, Kathleen <Deener.Kathleen@epa.gov> wrote:

Hopefully provisions for independent peer review, too.

Kacee Deener, MPH

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From: Burke, Thomas
Sent: Thursday, June 30, 2016 6:04 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Cc: Kavlock, Robert <Kavlock.Robert@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>
Subject: Re: This should be interesting

Deliberative Process / Ex. 5

Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator
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Office of Research and Development
Personal Matters / Ex. 6
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On Jun 30, 2016, at 4:48 PM, Bahadori, Tina <Bahadori.Tina@epa.gov> wrote:

Risk Assessment
Third Parties Can Give EPA Draft Chemical Risk Evaluations
<image001.png>

BNA Snapshot

- TSCA amendments require the EPA to prepare guidance for chemical risk evaluations interested parties submit.
- The provision allows parties to influence the agency's decision.
- The evaluation may flag risks in time for companies to obtain data.

By Pat Rizzuto

June 29 — Chemical manufacturers, consultants and other parties can submit draft risk evaluations of chemicals to the Environmental Protection Agency under the newly amended chemicals law, industry attorneys say.

The EPA must develop guidance for the third-party developed risk evaluations within one year of the Toxic Substances Control Act amendments' enactment, Mike Walls, vice president of regulatory and technical affairs at the American Chemistry Council, said June 28 during an American Bar Association luncheon.

He referred to Section 17 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amends Section 26 of TSCA. President Barack Obama signed the chemical reform bill, which amended TSCA, into law on June 22.

What's in the Law?

Under the amended Section 26: “the administrator shall develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the administrator.

“The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the administrator.”

After his presentation, Walls told Bloomberg BNA the guidance will be important to all stakeholders, but particularly for manufacturers with substances that the agency is evaluating.

Under the amended law, the agency must reevaluate the risks of chemicals it designates to be high priorities due to their persistence, toxicity or other characteristics.

Chemical manufacturers and trade associations also can request the agency to evaluate chemicals if they pay for some or all of the agency's costs.

Assessments' Usefulness

"The draft risk assessments can help consolidate and integrate hazard, exposure and risk information, and ultimately help EPA make efficient decisions on the substances under review," Walls told Bloomberg BNA by e-mail.

"In that way, the draft risk assessments can help accelerate the 'throughput' in the system and help augment the resources that the agency would otherwise have to commit," he said.

Walls said any interested person may submit a draft risk evaluation to the agency for it to consider as part of its work on a particular chemical.

"I think that's a potentially very powerful tool for any stakeholder," Walls said at the ABA meeting. "You can bring information that could influence the EPA's decision on a substance."

Evaluations Could Flag Risks

Judah Prero, a former American Chemistry Council attorney who now works with Sidley Austin LLP in Washington, told Bloomberg BNA the agency's guidance will enable interested parties to know, with a degree of certainty, what the EPA is looking for and what the agency will require in a risk evaluation.

At a minimum, he said, that gives interested parties the "power of the pen."

A chemical manufacturer, for example, "can make sure that all relevant information is included and conduct its own literature reviews or searches for relevant studies," Prero said by e-mail.

"While EPA will use whatever information it has, and can order testing, at the end of the day, EPA only has what it has. It is possible for a study or some information not to make its way to EPA," he said.

A third party can conduct an exhaustive search, weigh and incorporate all information and characterize the results, Prero said.

Can Provide Comfort, Warning to Company

"That can either provide comfort to a company, knowing that all seems to be in order, or it can give a company advance warning that issues exist, and the company then has time to deal with the issue prior to EPA taking regulatory action," Prero said.

Paying for a risk evaluation is a significant investment, he said.

"If done well, it can only help—as it will serve as solid evidence of safety, or provide knowledge of issues that need to be addressed," Prero said.

"While keeping one's head in the sand might help to allow that entity to think nothing is wrong, I personally believe that a company is better served when it tackles an issue when it surfaces as a result of their own due diligence, and not due to a discovery by a regulator," Prero continued.

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